NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE K-DUR ANTITRUST LITIGATION	**Civil Action No. 01-cv-1652 (SRC)(CLW)**
This document relates to:	**MDL Docket No. 1419**
All Actions	**OPINION**

CHESLER, District Judge

This matter comes before the Court upon three motions: (1) Defendants Merck & Co., Inc. and Upsher-Smith Laboratories' ("Defendants") motion for summary judgment as to all claims brought by Direct Purchaser Plaintiffs ("Plaintiffs") related to the Upsher-Smith settlement [Docket Entry 839]; (2) Defendants' motion for summary judgment as to all claims brought by Plaintiffs related to the ESI settlement [Docket Entry 840]; and (3) Plaintiffs' motion to strike Sections I and II of the reply memorandum submitted by Defendant Merck & Co., Inc., in support of its motion for summary judgment on all claims related to the ESI settlement [Docket Entry 848]. The Court has considered the papers filed by the parties, and heard oral argument on these motions on July 22, 2015 [Docket Entry 859]. For the reasons discussed below, the Court will deny Plaintiffs' motion to strike Sections I and II of Defendants' reply memorandum related to the ESI settlement. The Court will also deny Defendants' motion for summary judgment as to all claims brought by Plaintiffs related to the Upsher-Smith settlement.

The Court will grant Defendants' motion for summary judgment as to all claims brought by Plaintiffs related to the ESI settlement.

I. INTRODUCTION

Plaintiffs in this action challenge the lawfulness of two patent litigation settlements between a brand-name pharmaceutical company and generic pharmaceutical companies who sought to enter the market with generic drugs, prior to expiration of the brand-name manufacturer's relevant patent for the drug. In the events leading to this case, brand-name pharmaceutical manufacturer Schering-Plough Corporation ("Schering") settled two separate patent infringement litigation cases with generic manufacturers Upsher-Smith Laboratories ("Upsher") and ESI-Lederle ("ESI"), related to Schering's sustained-release potassium supplement K-Dur. These settlements provided for cash payments from Schering to each generic company, in exchange for the generic company's promise to not enter the market with a generic version of K-Dur for a period of time.

The type of settlement described above is commonly known as a reverse payment settlement, or a "pay-for-delay" settlement. Reverse payment settlements typically occur between brand-name pharmaceutical companies, who ordinarily hold the patents at issue in patent infringement litigation, and generic pharmaceutical companies, who seek to compete in the same drug market as the brand-name company and thus run the risk of infringing the brand-name company's patents. In a reverse payment settlement, the patent holder pays the generic company (also usually an alleged patent infringer) substantial consideration, in exchange for the generic company's agreement to settle the patent litigation and delay entry into the market for a set period of time. Reverse payment settlements occur almost exclusively in pharmaceutical drug

litigation, usually under the auspices of the Hatch-Waxman Act's provisions allowing generic manufacturers to challenge the validity of a patent owned by a brand-name manufacturer. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2227-28 (2013).

Plaintiffs allege that the settlements between Schering and Upsher ("the Schering-Upsher settlement") and Schering and ESI ("the Schering-ESI settlement") were anticompetitive agreements that prevented and delayed the market entry of generic substitutes for K-Dur, and that Schering, Upsher, and ESI engaged in a conspiracy to restrain trade of K-Dur and to fix the price of K-Dur, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. (First Am. Class Action Compl. ¶¶ 119-22, Docket Entry 839-4).

This case has had a long factual and procedural history, which has been recounted in numerous previous opinions. The relevant regulatory and procedural background, as well as the facts germane to the motions addressed in this Opinion, are reviewed below.

a. REGULATORY BACKGROUND

A brand-name drug manufacturer seeking to market a "pioneer" new prescription drug in the United States first must file a New Drug Application ("NDA") with the federal Food and Drug Administration ("FDA"). 21 U.S.C. § 355(b)(1) (2012); *Actavis*, 133 S. Ct. at 2228. The brand-name manufacturer must then provide data to the FDA to verify the safety and efficacy of the new drug, and must also provide the FDA with information on how the drug is manufactured, processed, and packed. *Id.* This information is printed in the publication Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book." FDA Electronic Orange Book, http://www.fda.gov/cder/ob/. The FDA may grant a brand-name

manufacturer permission to market the pioneer drug in the United States, after a review process. 21 U.S.C. § 355(b)(1); *Actavis*, 133 S. Ct. at 2228.

Regulation of the approval of generic drugs in the United States is governed by the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act. Pub. L. 98-419, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc, 35 U.S.C. §§ 156, 271), *amended by* the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003). The Hatch-Waxman Act permits generic manufacturers to avoid the long and expensive process of obtaining FDA approval for a pioneer brand-name drug. After the FDA has approved a pioneer brand-name drug for marketing, a generic drug manufacturer can file an Abbreviated New Drug Application ("ANDA") with the FDA to seek marketing approval. The ANDA applicant must declare that the generic drug has the "same active ingredients" as and is biologically equivalent to the brand-name drug. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv)); *see also Actavis*, 133 S. Ct. at 2228.

The Hatch-Waxman Act also provides special procedures for patent disputes arising between brand-name manufacturers and generic manufacturers. For example, brand-name manufacturers are required to list the patent number and expiration date for any relevant patents for the drug in the NDA. 21 U.S.C. § 355(b)(1); *Actavis*, 133 S. Ct. at 2228. In addition, generic manufacturers must provide written notice to each patent owner listed in the Orange Book who may be impacted by an ANDA. 21 U.S.C. § 355(j)(2)(B)(iii)(I). Generic manufacturers also must assert in the ANDA that the generic drug does not infringe the brand-name drug's patents, and may do so in a variety of ways. *Actavis*, 133 S. Ct. at 2228 (citing *Caraco*, 132 S. Ct. at

1672). A generic manufacturer may assert that the brand-name manufacturer has not listed any relevant patents in its NDA, or that any relevant patents listed in the NDA have expired. 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)-(II). It may request approval to market its generic drug once the brand-name drug's patents expire. 21 U.S.C. §§ 355(j)(2)(A)(vii)(III). Finally, under a certification commonly known as the "Paragraph IV route," it may certify that any relevant patent listed in the NDA "is invalid or will not be infringed by the manufacture, use, or sale" of the generic drug listed in the ANDA. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Using the Paragraph IV route in an ANDA application is an automatic act of patent infringement (per 35 U.S.C. § 271(e)(2)(A)), and oftentimes spurs the brand-name patent holder to start litigation proceedings against the generic ANDA filer. *Actavis*, 133 S. Ct. at 2228 (citing *Caraco*, 132 S. Ct. at 1677). When the brand-name manufacturer brings an infringement suit against the ANDA applicant within 45 days of a Paragraph IV filing, the FDA may not grant final approval of the generic drug until either (1) 30 months has passed, or (2) the court hearing the patent infringement or validity suit has found that the patent is either invalid or not infringed, whichever is earlier. 21 U.S.C. § 355(j)(5)(B)(iii)(I).

Under the current Hatch-Waxman Act provisions, the first generic manufacturer to file an ANDA application is entitled to 180 days of marketing exclusivity over other generic companies, starting on (1) the first day it commercially markets its generic drug, or (2) from the date of a court decision[1] of patent invalidity or non-infringement. 21 U.S.C. § 355(j)(5)(B)(iv). If a first-

[1] The meaning of "court decision" has been refined by the courts over time. At the time of the Schering-Upsher and Schering-ESI settlements, the FDA applied the interpretation that a court decision on validity or non-infringement had been rendered either when the Federal Circuit affirmed a district court decision, or when the time for filing an appeal had lapsed. In *Mylan Pharmaceuticals, Inc. v. Shalala*, 81 F. Supp. 2d 30, 41-42 (D.D.C. 2000), the court held that "decision of a court" meant "all court decisions, whether subsequently vacated, settled, appealed or

to-file generic company forfeits the exclusivity right for a particular drug, no other generic company can receive it. 21 U.S.C. § 355(j)(5)(D). Generic companies value this exclusivity right highly; oftentimes most of the profits a generic company makes on a particular generic drug are earned during the exclusivity period. *See, e.g.*, C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1588-94 (2006).

Starting in the late 1990s, some parties to patent infringement suits under the Hatch-Waxman regime began to settle their disputes using reverse payment settlements, where the brand-name patent holder gave valuable consideration to the generic manufacturer, primarily in exchange for the generic manufacturer's agreement to refrain from entering the market with a generic drug for a set period of time. Congress observed that many of these agreements may have potentially anticompetitive elements, and thus amended the Hatch-Waxman Act as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to require parties who settle patent litigation under the Hatch-Waxman Act to submit their settlement agreements to the Federal Trade Commission and the Department of Justice for antitrust review. Pub. L. No. 108-173, §§ 1111-1118, 117 Stat. 2066, 2461-64 (codified as amended at 21 U.S.C. § 355(j)).

otherwise mooted," and that the 180-day exclusivity period began on the date a district court rendered a decision of patent invalidity, non-infringement, or unenforceability. The FDA acknowledged that it would follow this approach prospectively in its March 2000 Guidance to Industry on this topic.

b. FACTUAL AND PROCEDURAL BACKGROUND OF SCHERING'S SETTLEMENTS WITH UPSHER AND ESI[2]

i. PARTIES

Lead Plaintiff Louisiana Wholesale Drug represents the Direct Purchaser Plaintiff class in this action, comprised of all persons or entities who purchased K-Dur directly from Schering from November 20, 1998 through September 1, 2001. (First Am. Class Action Compl. ¶ 2, Docket Entry No. 839-4.) Direct Purchaser Plaintiffs include direct purchasers of K-Dur, as well as health maintenance organizations, hospitals, retail drug store chains, and wholesalers. (*Id.*)

Former Defendant Schering was a New Jersey corporation involved in drug discovery, development, and marketing of brand-name and generic drugs. (*Id.* ¶ 3.) Schering merged with Defendant Merck in 2009. Defendant Upsher is a Minnesota corporation involved in drug discovery, development, and marketing of brand-name and generic drugs. (*Id.* ¶ 4.) Former Defendant Wyeth Laboratories ("Wyeth"), previously known as American Home Products, Inc. ("AHP"), was a Delaware corporation involved in drug discovery, development, and marketing of brand-name and generic drugs. (*Id.* ¶ 5.) Former Defendant ESI was a business unit of Wyeth, engaged in the research, manufacture, and sale of generic drugs. (*Id.*)

ii. K-DUR AND SCHERING'S '743 FORMULATION PATENT[3]

In the time period before the events leading to this litigation, Schering marketed a brand-name sustained-release potassium chloride supplement known as K-Dur. (Defs.' SUF Upsher ¶

[2] The facts pertinent to the current motions are drawn primarily from the parties' pleadings and respective statements filed pursuant to Local Rule 56.1.

[3] The details of this patent and its prosecution are described in the Special Master's 2009 Report and Recommendation in this case. *In re K-Dur Antitrust Litig.*, No. 1-1652, 2009 WL 508869, at *4-5 (D.N.J. Feb. 6, 2009).

1; Pls.' SDF Upsher ¶ 1.) The compound potassium chloride itself could not be patented due to prior art in the field. (Pls.' SDF Upsher ¶ 2; Defs.' SDF Reply Upsher ¶ 2.) Schering's subsidiary Key Pharmaceuticals ("Key") held a formulation patent (U.S. Patent No. 4,863,743 ("the '743 patent")) on the controlled-release coating used to package the potassium chloride crystals. (Defs.' SUF Upsher ¶ 2; Pls.' SDF Upsher ¶¶ 2, 55; Defs.' SDF Reply Upsher ¶ 55.) Schering listed the '743 patent in the Orange Book, as a patent that would be infringed by a generic version of K-Dur. (Pls.' SDF Upsher ¶ 56; Defs.' SDF Reply Upsher ¶ 56.) The '743 patent expired on September 5, 2006. (Defs.' SUF Upsher ¶ 2; Pls.' SDF Upsher ¶ 2.)

iii. SCHERING'S PATENT LITIGATION AND SETTLEMENT WITH UPSHER

Upsher filed the first ANDA related to K-Dur in August 1995, seeking approval for its generic version of K-Dur: a microencapsulated, controlled-release potassium chloride tablet. (Defs.' SUF Upsher ¶ 3; Pls.' SDF Upsher ¶ 3.) In its Paragraph IV certification, Upsher claimed that its generic drug was bioequivalent to K-Dur, but did not infringe the '743 patent. (Defs.' SUF Upsher ¶¶ 4-6, Pls.' SDF Upsher ¶¶ 4-6, 57; Defs.' SDF Reply Upsher ¶ 57.)

Schering (through Key) then filed a patent infringement suit against Upsher in the District of New Jersey on December 15, 1995, seeking to enjoin Upsher from marketing its generic version of K-Dur until the '743 patent expired in September 2006. (Defs.' SUF Upsher ¶ 7; Pls.' SDF Upsher ¶¶ 7, 58; Defs.' SDF Reply Upsher ¶ 58.) Upsher denied the infringement claims, and brought declaratory judgment counterclaims for invalidity, non-infringement, and unenforceability of the '743 patent. (Defs.' SUF Upsher ¶ 8; Pls.' SDF Upsher ¶ 8.)

The parties reached a settlement on the morning of June 18, 1997 ("the Schering-Upsher settlement," dated June 17, 1997), on the eve of trial in the patent litigation action. (Defs.' SUF

Upsher ¶¶ 14-20, 27, 43-44; Pls.' SDF Upsher ¶¶ 14-20, 27, 43-44, 64-74, 76; Defs.' SDF Reply Upsher ¶¶ 64-74, 76.) The settlement included the following main terms: (1) Upsher would not market its generic potassium chloride drug or any other sustained-release microencapsulated potassium chloride tablet before September 1, 2001; (2) effective September 1, 2001, Schering would grant Upsher a non-exclusive, non-royalty bearing license to market its generic potassium chloride products in the United States; (3) Upsher granted Schering an overseas license to Niacor-SR© ("Niacor"), a sustained-release niacin drug, as well as five other products[4]; and (4) Schering agreed to pay Upsher $60 million in three installments over two years, up to a further $10 million in milestone payments upon marketing of Niacor in certain countries, and 10 to 15 percent royalties on net Niacor sales.[5] (Defs.' SUF Upsher ¶ 43; Pls.' SDF Upsher ¶ 43; Docket Entry 843, Ex. 1.)

iv. SCHERING'S LITIGATION, MEDIATION, AND SETTLEMENT WITH ESI

On December 29, 1995, ESI filed an ANDA application on a sustained-release potassium chloride version of K-Dur, including a Paragraph IV certification. (Defs.' SUF ESI ¶ 1; Pls.' SDF ESI ¶ 1.) Schering (through Key) subsequently sued ESI in the Eastern District of Pennsylvania on February 16, 1996, alleging infringement of the '743 patent. (Defs.' SUF ESI ¶ 2; Pls.' SDF ESI ¶ 2.) Schering and ESI proceeded to court-supervised mediation in the fall of

[4] As a part of the Schering-Upsher settlement, in addition to the Niacor license Upsher granted Schering licenses to its products KLOR CON© 8, KLOR CON© 10, KLOR CON© M20, PREVALITE©, and pentoxifylline. (Docket Entry 843, Ex. 1.)

[5] Schering paid Upsher $28 million upon approval of the settlement by Schering's Board of Directors, $20 million on the first anniversary of the approval of the settlement, and $12 million on the second anniversary of the approval of the settlement. The settlement included payment schedules for milestones and royalties related to Schering's sales of Niacor, but Schering did not pursue the production and marketing of Niacor so these payments were never made. (Docket Entry 843, Ex. 1.)

1996, on the suggestion of presiding District Judge Jan DuBois. (*Id.*) United States Magistrate Judge Thomas Rueter served as mediator in this case, and met with the parties separately and jointly to encourage settlement. (*Id.*)

Judge DuBois held a *Markman* hearing on January 21 and 22, 1998, after which he directed the parties to Magistrate Judge Rueter to attempt to settle the case.[6] (Defs.' SUF ESI ¶¶ 11-13; Pls.' SDF ESI ¶¶ 11-13.) The parties eventually settled on the following terms on January 23, 1998 ("the Schering-ESI settlement"): (1) ESI agreed that it would not enter the K-Dur market with a generic product until January 1, 2004; (2) Schering would grant ESI a royalty-free, non-exclusive license of the '743 patent starting on January 1, 2004; (3) Schering would pay ESI $5 million upfront; and (4) Schering would pay ESI additional cash, the amount depending on when the FDA approved ESI's ANDA application for generic K-Dur. (Defs.' SUF ESI ¶¶ 15-18; Pls.' SDF ESI ¶¶ 15-18, 22; Defs.' SDF Reply ESI ¶ 22; Docket Entry 843-52.) Schering agreed to pay ESI a maximum of $10 million if the FDA approved ESI's ANDA before July 1999. (Defs.' SUF ESI ¶¶ 16-18; Pls.' SDF ESI ¶¶ 16-18, 22; Defs.' SDF Reply ESI ¶ 22; Docket Entry 843-52.) If the FDA did not approve ESI's ANDA until 2002, Schering agreed to pay ESI only $625,000. (*Id.*)

The FDA approved ESI's generic K-Dur product in May 1999, and Schering paid ESI the $10 million specified by the Schering-ESI settlement. (Defs.' SUF ESI ¶ 20; Pls.' SDF ESI ¶ 20.) In July 2001, ESI announced that it was exiting the oral generics business, and ESI left the oral generics market in 2002 without ever marketing a generic K-Dur product. (Defs.' SUF ESI

[6] The parties dispute the admissibility and relevance of comments made by Judge Rueter and Judge DuBois during the mediation process. (Defs.' SUF ESI ¶¶ 5, 11-19; Pls.' SDF ESI ¶¶ 5, 11-19.)

¶ 21; Pls.' SDF ESI ¶ 21.)

c. PROCEDURAL HISTORY

i. FTC ACTION AND APPEAL TO THE ELEVENTH CIRCUIT

On March 30, 2001, the FTC's Complaint Counsel filed a Complaint against Schering, Upsher, and AHP.[7] *In the Matter of Schering-Plough Corp.*, No. 9297, Initial Decision, 136 F.T.C. 956, 1092 (2002). The Complaint alleged that Schering's settlements with Upsher and ESI violated Section 5 of the Federal Trade Commission Act, because Schering, Upsher, and ESI entered into unlawful agreements to delay the entry of generic K-Dur onto the market. *Id.*

The FTC held a nine week trial in this action in early 2002, and at its conclusion the Administrative Law Judge ("ALJ") presiding over the case dismissed the Complaint, because he found no evidence to support the FTC's challenge on either settlement. *Id.* at 1092, 1263. The ALJ determined that the Schering-Upsher settlement did not include a reverse payment, because the parties separately valued the Niacor license deal included in the settlement. *Id.* at 1168-80. Thus, the ALJ concluded that Schering did not pay Upsher impermissibly for delaying its entry onto the market. *Id.* at 1243. The ALJ also found that the Schering-ESI settlement did not maintain Schering's monopoly unlawfully in the potassium chloride market. *Id.* at 1236, 1262-63.

The ALJ adopted the antitrust rule-of-reason approach to analyze the legality of both settlements.[8] In doing so, the ALJ rejected the FTC's preferred *per se* approach, which presumes that such settlements are illegal due to the need to consider the exclusionary power of the patent

[7] As noted above, ESI was a division of AHP, engaged in the manufacture, research, and sale of generic drugs. AHP became Wyeth in 2002. (First Am. Class Action Compl. ¶ 5.)
[8] The details of the rule-of-reason approach are reviewed in Section III.

in the analysis of the legality of the settlements. *Id.* at 1225-35. The ALJ found "no basis in law or fact" to make the presumption that the '743 patent was invalid, or that Upsher and ESI's products did not infringe the patent. *Id.* at 1097. Overall, the ALJ rejected the FTC's argument that without Schering's payments to Upsher and ESI, the generic companies could have entered the market earlier, given the exclusionary power of Schering's '743 patent and the court's inability to predict the outcome of the patent litigations at issue. *Id.* at 1193-94.

The full Federal Trade Commission ("the Commission") unanimously reversed the ALJ's decision in December 2003. *In the Matter of Schering-Plough Corp.*, Final Order, 136 F.T.C. 956, 1003-04 (2003). On its own fact findings, the Commission determined that Schering's $60 million payment compensated Upsher not only for the Niacor license but also for its delayed entry onto the K-Dur market. *Id.* at 1061. The Commission also determined that the Schering-ESI agreement violated the antitrust laws, given that Schering did not effectively rebut the presumption that the purpose of its payment to ESI was to guarantee ESI's delayed entry into the market. *Id.* at 1056-57. Although the Commission did not hold that Schering's payments to Upsher and ESI were *per se* illegal, it also did not adopt the rule-of-reason analysis used by the ALJ. *Id.* at 965. Instead, the Commission required the FTC's Complaint Counsel to first demonstrate that the agreements had anticompetitive effects, after which the "[r]espondents must demonstrate that the challenged provisions are justified by procompetitive benefits that are both cognizable and plausible." *Id.* The Commission found that the FTC's Complaint Counsel had demonstrated the Schering-Upsher and Schering-ESI settlements had anticompetitive effects, and found that with inadequate procompetitive justifications on the record, "it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the

date that represents an otherwise reasonable litigation compromise." *Id.* at 988. The Commission essentially concluded that settlements with reverse payments in excess of $2 million (to cover estimated legal fees) paid for market delay, and were thus illegal. *Id.* at 968.

On appellate review, the United States Court of Appeals for the Eleventh Circuit reversed the Commission's Final Order and dismissed the Complaint. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006). Rather than using a *per se* or a rule-of-reason approach, the Eleventh Circuit found that courts must determine "the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection." *Id*. at 1065, 1076. Under this rule, the settlements at issue fell within the protections of the '743 patent, and thus were not illegal. *Id.* at 1076. The Eleventh Circuit determined specifically that the $60 million payment in the Schering-Upsher settlement did not constitute an illegal reverse payment. In fact, the court found by "overwhelming evidence" that Schering's payment was for the license. *Id.* at 1069-71. Furthermore, although the court found that the Schering-ESI settlement included a reverse payment, given policy rationales favoring the settlement of litigation, the court found that this payment "'reflect[ed] a reasonable implementation' of the protections afforded by patent law." *Id.* at 1072 (quoting *Valley Drug Co. v. Geneva Pharms., Inc*., 344 F.3d 1294, 1312 (11th Cir. 2003)). These settlements allowed Upsher to enter the market more than five years before the '743 patent expired, and allowed ESI to enter the market more than two years before the '743 patent expired. *Id.* at 1067-68. At the time, no allegations had been raised that the '743 patent was invalid, or that Schering's infringement suits against the generic companies were shams. *Id.* at 1068. In addition, the court found no evidence on the record to support the Commission's conclusion that the parties would have compromised on

earlier entry dates without Schering's payments. *Id.* at 1074. The court further noted that the Hatch-Waxman Act changes the risk assessment for brand-name and generic manufacturers:

> [T]he Hatch–Waxman Amendments grant generic manufacturers standing to mount a challenge without incurring the cost of entry or risking enormous damages flowing from any possible infringement. Hatch–Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Because of the Hatch–Waxman scheme, ESI and Upsher gained considerable leverage in patent litigation: the exposure to liability amounted to litigation costs, but paled in comparison to the immense volume of generic sales and profits. This statutory scheme could then cost Schering its patent.
>
> By entering into the settlement agreements, Schering realized the full potential of its infringement suit—a determination that the '743 patent was valid and that ESI and Upsher would not infringe in the future. Furthermore, although ESI and Upsher obtained less than they what they would have received from successfully defending the lawsuits (the ability to immediately market their generics), they gained more than if they had lost. A conceivable compromise, then, directs the consideration from the patent owner to the challengers.

Id. (internal citations omitted). Under this logic, the Eleventh Circuit explicitly stated that settlements should be available as a remedy for brand-name and generic companies involved in Hatch-Waxman litigation, and should not be prevented due to the presence of a reverse payment—even when the payment is large. *Id.* at 1075.

ii. PRIVATE DAMAGES CASES

The action currently before this Court stems from private damage cases filed in 2001, after the FTC filed its Complaint against Schering, Upsher, and AHP (of which ESI was a subsidiary). Plaintiffs originally filed these cases in several districts, but the Judicial Panel on Multi-District Litigation consolidated the pending action in the District of New Jersey. *In re K-Dur Antitrust Litig.*, 176 F. Supp. 2d 1399 (J.P.M.L. 2001). By consent in 2006, the district court

appointed Stephen Orlofsky as Special Master, with the responsibility of handling all motions in this case [Docket Entry 316]. On April 14, 2008, the Special Master certified a class of plaintiffs of wholesalers and retailers who purchased K-Dur directly from Schering. *In re K-Dur Antitrust Litig.*, No. 1-1652, 2008 WL 2699390, at *1 (D.N.J. April 14, 2008).

Defendants Schering and Upsher filed summary judgment motions in 2008, asserting that to raise concerns about antitrust liability, Plaintiffs had to demonstrate either that Schering's underlying patent litigation was baseless, that the '743 patent was obtained by fraud, or that the settlement terms extended beyond the "scope of the patent." *In re K-Dur Antitrust Litig*., No. 01-1652 (JAG), 2009 WL 508869, at *12 (D.N.J. Feb. 6, 2009). Specifically on the Schering-Upsher settlement, Defendants also asserted that the evidence on the record was legally insufficient to prove that Schering's $60 million payment was anything other than a bona fide licensing payment for Niacor. *Id.* The Special Master recommended that summary judgment be granted for Defendants on these motions, because the settlements at issue were lawful under the "scope of the patent" test. *Id.* at *27-30. The opinion applied the presumption that the '743 patent was valid, and that Schering had, by right, the ability to exclude others from making infringing products until patent expiration, even through the use of reverse payments. *Id*. Under this framework, these settlements would be subject to antitrust scrutiny only if they exceeded the scope of the '743 patent, or if the underlying patent infringement suits were baseless. In this case, the Special Master found that neither of these exceptions applied. *Id.* On March 24, 2010, after *de novo* review, the Court adopted the Special Master's report and recommendation. *In re K-Dur Antitrust Litig.*, No. 01-1652, 2010 WL 1172995 (D.N.J. Mar. 24, 2010).

In 2012, the Third Circuit reversed the district court's decision on the issue of the proper test to use to determine antitrust liability. [9] *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012). In doing so, the court adopted the "quick look" test for the analysis of the potential antitrust liability of reverse payment settlements, which requires that the plaintiff initially present proof of a payment from a patent holder to a would-be generic entrant onto the market, after which the overall burden of proof shifts to the defendant to demonstrate that the payment was justified. *Id.* The Third Circuit explicitly rejected the "scope of the patent" test, stating that "litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers," and that although the "scope of the patent" test encourages settlements, courts must consider other factors when determining the legality of a settlement. *Id.* The Third Circuit noted that "the only settlements subject to antitrust scrutiny [under the 'quick look' test] are those involving a reverse payment from the brand-name manufacturer to the generic challenger," and that the vast majority of pharmaceutical settlements would be unaffected by this rule. *Id.*

Following the Third Circuit's 2012 decision, Defendants Merck and Upsher filed petitions for certiorari, based on a circuit split as to the applicable standard under which reverse payment settlements should be analyzed. Brief of Petitioner for Certiorari, *Merck & Co. v. La. Wholesale Drug Co.*, No. 12-245, 133 S. Ct. 2849 (Aug. 24, 2012); Brief of Petitioner for Certiorari, *Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co.*, No. 12-265, 133 S. Ct. 2849 (Aug. 29, 2012). To settle the circuit split, the Supreme Court granted certiorari on a reverse

[9] The Third Circuit also affirmed the district court's certification of the Direct Purchaser Plaintiff class. *In re K-Dur Antitrust Litig.*, 686 F.3d at 224.

payment settlement case from the Eleventh Circuit. *FTC v. Watson Pharms.*, 133 S. Ct. 787 (2012), *sub nom. FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). In *FTC v. Actavis, Inc.*, the Supreme Court directed lower courts to analyze reverse payments settlements using the rule-of-reason standard, and rejected both the "scope of the patent" and "quick look" tests. *Id.* at 2237. The Court held that "a reverse payment, where large and unjustified, can bring with it a risk of significant anticompetitive effects." *Id.* at 2237. Section III details the *Actavis* decision and its application to the analysis of reverse payment settlements.

Following the decision in *Actavis*, the Supreme Court granted Defendants' petitions for certiorari, vacated the Third Circuit's 2012 decision, and remanded the case to the Third Circuit. *Merck & Co. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013); *Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013). At the request of all parties, the Third Circuit remanded the case to this Court for further proceedings. *In re K-Dur Antitrust Litig.*, Nos. 10-2077, 10-2078, 10-4571, 2013 WL 5180857 (3d Cir. Sept. 9, 2013).

Currently before this Court are three motions: (1) Defendants' motion for summary judgment on all claims related to the Schering-Upsher settlement; (2) Defendants' motion for summary judgment on all claims related to the Schering-ESI settlement; and (3) Plaintiffs' motion to strike sections I and II of the reply memorandum submitted by Defendant Merck & Co., Inc. in support of its motion for summary judgment on all claims related to the ESI settlement. The Court heard oral argument on all motions on July 22, 2015 [Docket Entry 859].

II. LEGAL STANDARD FOR SUMMARY JUDGMENT

Summary judgment is appropriate under Fed. R. Civ. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the

moving party's entitlement to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" *Marino v. Indus. Crating Co.*, 358 F.3d 241, 247 (3d Cir. 2004) (quoting *Anderson*, 477 U.S. at 255).

"When the moving party has the burden of proof at trial, that party must show affirmatively the absence of a genuine issue of material fact: it must show that, on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party." *In re Bressman*, 327 F.3d 229, 238 (3d Cir. 2003) (quoting *United States v. Four Parcels of Real Prop.*, 941 F.2d 1428, 1438 (11th Cir. 1991)). "[W]ith respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party's case." *Celotex*, 477 U.S. at 325.

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. *Jersey Cent. Power & Light Co. v. Lacey Twp.*, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations and instead must present actual evidence that creates a genuine issue as to a material fact for trial. *Anderson*, 477 U.S. at 248; *Siegel Transfer, Inc. v.*

Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). "[U]nsupported allegations . . . and pleadings are insufficient to repel summary judgment." *Schoch v. First Fid. Bancorporation*, 912 F.2d 654, 657 (3d Cir. 1990); *see also* Fed. R. Civ. P. 56(e) (requiring the nonmoving party to "set out specific facts showing a genuine issue for trial"). "A nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial." *Gleason v. Norwest Mortg., Inc.*, 243 F.3d 130, 138 (3d Cir. 2001).

If the nonmoving party has failed "to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial, . . . there can be 'no genuine issue of material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Katz v. Aetna Cas. & Sur. Co.*, 972 F.2d 53, 55 (3d Cir. 1992) (quoting *Celotex*, 477 U.S. at 322-23).

III. Standard for Establishing Antitrust Liability under *Actavis*

The parties spend significant effort in their briefing on these motions debating how *Actavis* and the rule of reason should be applied in reverse payment settlement cases. This Section outlines the Court's views on these topics.

a. Reverse Payment Settlements: The *Actavis* Decision

In *Actavis*, the Supreme Court directed lower courts to use the antitrust rule of reason to examine the legality of reverse payment settlements on a case-by-case basis. *Id.* at 2236-37. In doing so, it explicitly rejected both the "scope of the patent" and the "quick look" tests for determining antitrust liability of reverse payment settlements. *Id.* at 2225, 2236-37. The Court identified five main considerations in its decision: (1) reverse payment settlements have the

"potential for genuine adverse effects on competition"; (2) the anticompetitive results of these settlements may sometimes be unjustified, for example where payments are not intended only to offset litigation costs; (3) patent holders often possess the market power necessary to cause anticompetitive harm; (4) litigating patent validity may not be necessary to determine whether a settlement is legal under antitrust laws, as "large and unexplained" reverse payment settlements indicate that the patent holder has doubts about the patent's ability to withstand scrutiny; and (5) parties can still settle patent litigation, despite the risk of antitrust scrutiny, by avoiding reverse payment settlements. *Id.* at 2234-37.

The FTC encouraged the Supreme Court to adopt the "quick look" test for the analysis of potential antitrust liability for reverse payment settlements. This test shifts the burden of proof to the defendant to show procompetitive effects of the reverse payment settlement in question. *Id.* at 2237. The Supreme Court declined to do so, and cited *California Dental Association v. FTC* for the proposition that the rule of reason should be abandoned for the "quick look" test "only where 'an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.'" *Id.* (quoting *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999)). The Supreme Court stated that reverse payment settlements do not meet this criterion, given that:

> [T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among industries. These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases.

Id. The Supreme Court did explain, however, that the FTC need not "litigate the patent's validity, empirically demonstrate the virtues or vices of the patent system, present every possible supporting fact or refute every possible pro-defense theory" under the rule-of-reason approach. *Id.*

b. Application of *Actavis* to Rule of Reason Analysis

As noted above, in *Actavis*, the Supreme Court directed lower courts to analyze reverse payment settlements using the antitrust rule-of-reason test. *Id*. at 2237-38. "The true test of legality [under the rule-of-reason test] is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition." *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.2d 57, 75 (3d Cir. 2010) (quoting *Orson, Inc. v. Miramax Film Corp.*, 79 F.3d 1358, 1368 (3d Cir. 1996)). The traditional rule-of-reason analysis directs the finder of fact to:

> [W]eigh all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition. The plaintiff bears an initial burden under the rule of reason of showing that the alleged combination or agreement produced adverse, anti-competitive effects within the relevant product and geographic markets. The plaintiff may satisfy this burden by proving the existence of actual anticompetitive effects, such as reduction of output, increase in price, or deterioration in quality of goods or services. Such proof is often impossible to make, however, due to the difficulty of isolating the market effects of challenged conduct. Accordingly, courts typically allow proof of the defendant's market power instead. Market power, the ability to raise prices above those that would prevail in a competitive market, is essentially a surrogate for detrimental effects.
>
> If a plaintiff meets his initial burden of adducing adequate evidence of market power or actual anti-competitive effects, the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective. . . . To rebut, the plaintiff must demonstrate that the restraint is not reasonably necessary to achieve the stated objective.

United States v. Brown Univ., 5 F.3d 658, 668-69 (3d Cir. 1993) (alterations, citations, footnotes, and internal quotations omitted).

The Supreme Court left development of the application of the rule-of-reason test in reverse payment settlement cases primarily to the lower courts, indicating that lower courts should focus on the "basic question" of whether a settlement has "significant unjustified anticompetitive consequences." *Actavis*, 133 S. Ct at 2237. Recently, the Third Circuit directed a district court to apply the rule of reason as described in *Actavis*:

> First, to prove anticompetitive effects, the plaintiff must prove payment for delay, or, in other words, payment to prevent the risk of competition. [T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.
>
> Second, the burden then shifts to the defendant to show that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.
>
> > The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item. There may be other justifications.
>
> The Court does not foreclose other justifications, and we need not decide today what those other justifications might be.
>
> Finally, the plaintiff will have the opportunity to rebut the defendant's explanation.

King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 412 (3d Cir. 2015) (internal citations, quotations, and footnotes omitted). The Supreme Court gave lower courts further guidance on the application of the rule of reason to reverse payment settlement cases,

noting that antitrust considerations only arise if a "reverse payment" has occurred, and that the reverse payment in question must be "large and unexplained." *Actavis*, 133 S. Ct. at 2236-37. "Large" payment sums should be scrutinized more carefully, as a large payment may "provide a workable surrogate for a patent's weakness." *Id.* Reverse payment settlements also may be anticompetitive when the size of the settlement is too large when compared to the potential cost of future litigation, or where other reasonable justification for the settlement cannot be shown. *Id*. at 2237-38. Finally, the Supreme Court directed lower courts to consider "traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents." *King Drug*, 791 F.3d at 412 (quoting *Actavis*, 133 S. Ct. at 2231).

This Court notes that the rule-of-reason test puts the ultimate burden of proof to show anticompetitive conduct onto the plaintiff. Once the plaintiff establishes a prima facie case for antitrust liability, as described above, the defendant may rebut by showing why the conduct in question was procompetitive in nature. The "quick look" test, by contrast, creates the presumption that the conduct in question is in fact anticompetitive, thereby shifting the ultimate burden of proof to the defendant to show that the conduct in question is procompetitive.

Since the *Actavis* decision, several courts[10] have examined the application of the rule of reason to the context of reverse payment settlements. In particular, district courts in the District

[10] The questions of burdens and elements in a rule-of-reason analysis of reverse payment settlements have been addressed by two district courts prior to this Opinion: the Eastern District of Pennsylvania in *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402 (E.D. Pa. 2015); and the District of Massachusetts in *In re Nexium (Esomeprazole) Antitrust Litigation*, 42 F. Supp. 3d 231 (D. Mass. 2014). The California Supreme Court has also addressed the burdens required in examining a reverse payment settlement case under the rule of reason in *In re Cipro Cases I & II*, 348 P.3d 845 (Cal. 2015).

of Massachusetts and the Eastern District of Pennsylvania have examined the burdens held by each party at each stage of analysis.

First, the District of Massachusetts interpreted *Actavis* to apply to the examination of "large and unjustified" reverse payments. *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 262 (D. Mass. 2014). This court's theory of burden shifting under the rule of reason is as follows. The plaintiff must first demonstrate that the settlement in question included a payment from the brand-name to the generic company, and notes that "[t]he size and scale of such a payment . . . can be an indicator of anticompetitive intent, because '[a] large payment would be an irrational act unless the patentee believed that generic production would cut into its profits.'" *Id.* (quoting Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's* Actavis *Decision*, 15 Minn. J.L. Sci. & Tech. 3, 25 (2013)). If the plaintiff can make this showing, the burden shifts to the defendant to show that the payment may be justified by a procompetitive goal, such as avoided litigation costs or payment of fair value for services or goods rendered. *Id.* If the defendant shows a procompetitive justification for the payment, the burden shifts back to the plaintiff to show that, on balance, the settlement is anticompetitive. *Id.* at 262-63.

In *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, the Eastern District of Pennsylvania laid out a slightly different interpretation of *Actavis*, where the plaintiff must establish in the first step of the rule-of-reason analysis that the payment in question was "large." 88 F. Supp. 3d 402, 414 (E.D. Pa. 2015). Although the court did not impose a "threshold burden" on the plaintiff to show that the reverse payment is large and unjustified, it noted that "evidence of a large payment is required for a plaintiff to satisfy its initial burden of demonstrating anticompetitive effects

under the *Actavis* rule of reason analysis." *Id.* at 415. If the plaintiff can satisfy this burden, "the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently procompetitive objective . . . with the defendant bearing the burden of providing evidence that the reverse payment is justified by procompetitive considerations." *Id.* Should the defendant satisfy this burden, the plaintiff must rebut the defendant's justifications and "raise a genuine dispute of material fact as to the defendant's justifications," after which a finder of fact will weigh the anticompetitive and procompetitive effects of the agreement. *Id.*

If this Court adopted the approach espoused in these opinions, to satisfy their initial burden Plaintiffs would be required to produce evidence that a large amount of consideration (monetary or otherwise) had been transferred from the brand-name company (Schering) to a generic company, and that at least a component of the settlement compensated the generic company for delaying entry onto the market. Defendants would then bear the burden to show that the payment compensated the generic company for reasonable litigation costs and other products and services, given that "[f]ailure to provide a legitimate justification results in antitrust liability." *Id.* at 416. This Court is concerned that any sort of requirement for Plaintiffs to establish at the outset that a settlement payment in question was "large" creates a threshold burden not delineated under the rule of reason. Furthermore, this Court notes that the Supreme Court explicitly rejected the "quick look" test, so any analysis of the legality of a reverse payment settlement must place the overall burden to prove the settlement was anticompetitive onto Plaintiffs, and furthermore must put the initial burden of proof to establish a prima facie case in the first step of the rule-of-reason analysis onto Plaintiffs as well. Thus, the burden must be on Plaintiffs to show that the settlement delayed the generic company's entry onto the market,

that the brand-name company paid the generic company consideration of some kind, and that the consideration exchanged in the settlement exceeded the estimated cost of litigation and the costs of other services and products, in order to establish a prima facie case. Antitrust implications for a reverse payment only arise if the payment is separate from compensation for the fair market value of other products and services bargained for in the settlement, as well as the potential litigation costs that the settlement effectively saves.

This Court also believes that in most cases it is likely that the defendants will have better access to information about the value of the payments in question, including the value of products, services, and estimated litigation costs saved by the settlement. Although the plaintiff must bear the initial burden of proof to establish a prima facie case, it is logical that the defendant should bear the burden of production to present this evidence. If the defendant can show evidence on this issue, the plaintiff would then need to show that that the payment exceeded the value of litigation costs or other products or services to satisfy its overall burden in this step of the rule-of-reason analysis.

Given the above discussion, the Court finds the logic behind the burden shifting in the recent California Supreme Court decision *In re Cipro Cases I & II*, 348 P.3d 845 (Cal. 2015) [11] compelling. The California Supreme Court summarizes their application of the rule of reason to reverse payment settlement cases as follows:

> To make out a prima facie case that a challenged agreement is an unlawful restraint of trade, a plaintiff must show the agreement contains both a limit on the generic

[11] *In re Cipro Cases I & II* focuses on the application of *Actavis* to the Cartwright Act, California's state antitrust law. The Cartwright Act and the Sherman Act are not perfectly analogous, but both statutes have implied exceptions that "validate reasonable restraints of trade" under the rule of reason. *In re Cipro Cases I & II*, 348 P.3d at 855 (citing *Standard Oil Co. v. United States*, 221 U.S. 1 (1911); *People v. Bldg. Maint. Contractors' Ass'n, Inc.*, 264 P.2d 31 (Cal. 1953)).

> challenger's entry into the market and compensation from the patentee to the challenger. The defendants bear the burden [of production] of coming forward with evidence of litigation costs or valuable collateral products or services that might explain the compensation; if the defendants do so, the plaintiff has the burden of demonstrating the compensation exceeds the reasonable value of these. If a prima facie case has been made out, the defendants may come forward with additional justifications to demonstrate the settlement agreement nevertheless is procompetitive. A plaintiff who can dispel these justifications has carried the burden of demonstrating the settlement agreement is an unreasonable restraint of trade . . .

Id. at 871. This Court will adopt the framework outlined above in its analysis of these motions for summary judgment.

IV. DISCUSSION[12]

a. MOTION FOR SUMMARY JUDGMENT ON ALL CLAIMS RELATED TO THE SCHERING-UPSHER SETTLEMENT

Defendants have moved for summary judgment on all claims related to the Schering-Upsher settlement. The parties dispute two main points in their briefing: how burdens of proof operate under the rule of reason for each party post-*Actavis*, and whether Schering's payment for the Niacor license was indeed fair market value. The Court has addressed how it will apply the rule of reason in the previous Section, and will now examine whether Plaintiffs have satisfied

[12] Plaintiffs filed a motion to strike Sections I and II of Defendants' reply memorandum in support of the motion for summary judgment on all claims related to the Schering-ESI settlement, asserting that Defendants raised subjects in their reply brief that had not been raised in the moving papers for the motion for summary judgment [Docket Entry 848]. In particular, Plaintiffs objected to arguments related to the existence of a single conspiracy, and whether Plaintiffs could prove that Upsher's entry onto the market was delayed. Following oral argument on this motion on July 22, 2015 [Docket Entry 859], the Court permitted Plaintiffs and Defendants to submit sur-replies on the issues of whether Plaintiffs could prove a three-way conspiracy between Schering, Upsher, and ESI, and whether Plaintiffs could prove that entry of Upsher's generic K-Dur product was delayed by the alleged single conspiracy [Docket Entries 856, 858]. Considering that both parties have had the opportunity to address these arguments, the Court will deny Plaintiffs' motion to strike as moot, and will consider all briefing to decide these summary judgment motions.

their burden under the rule of reason sufficiently to survive summary judgment, with special focus on the factual issue of the fair market value of the Niacor license.

Plaintiffs have offered sufficient evidence such that a reasonable finder of fact could find that Plaintiffs have established a prima facie case for antitrust liability. Although Defendants have offered procompetitive justifications for the reverse payment settlement, particularly evidence that may indicate that Schering paid fair market value for the Niacor license, Plaintiffs have offered sufficient evidence such that a reasonable jury could conclude that Schering's payment to Upsher did not merely compensate Upsher for the fair market value of the Niacor license.

1. Plaintiffs' Prima Facie Case Under *Actavis*

To establish a prima facie case that the Schering-Upsher settlement was an unlawful restraint of trade, Plaintiffs must first show that the agreement limited Upsher's entry into the market for generic K-Dur, and that Schering paid Upsher as a part of the settlement. Once this is done, Defendants then have the burden of production (but not the ultimate burden of proof) to show the value of litigation costs, products, or services the settlement covered. If this is done, Plaintiffs then have the burden of proof to demonstrate that the compensation exceeded the reasonable value of litigation costs, products, and/or services. As noted earlier, if a finder of fact concludes that such a prima facie case has been made out, Defendants then can show evidence to demonstrate why the agreement is nevertheless procompetitive.

The parties do not dispute that the Schering-Upsher settlement did in fact limit Upsher's entry into the K-Dur market, as Upsher agreed to an entry date of September 1, 2001. (Defs.' SUF Upsher ¶ 19; Pls. SDF Upsher ¶ 19, Docket Entry 843, Ex. 1.) Furthermore, it is

undisputed that Schering paid Upsher $60 million as a term of the settlement. (Defs.' SUF Upsher ¶ 43; Pls.' SDF Upsher ¶ 43.) Defendants have put forth evidence that Schering's payment to Upsher paid for the license to Niacor, as well as other licenses, satisfying their burden of production on this issue. (Defs.' SUF Upsher ¶¶ 18, 21-51.) Plaintiffs have offered expert testimony showing that Schering's payment to Upsher exceeded the value of the Niacor license, in an attempt to discredit Defendants' evidence. (Pls.' SDF Upsher ¶¶ 72-149.) As outlined in more detail below, Plaintiffs' evidence on this point raises significant questions as to Defendants' justification for the value of the Schering-Upsher settlement payment. The Court concludes that there is indeed a genuine dispute of material fact as to whether Schering's payment exceeded the fair value of the licenses coupled with litigation costs. Accordingly, there is sufficient evidence on this record such that a reasonable finder of fact could find that Plaintiffs have established a prima facie case for antitrust liability as to the Schering-Upsher settlement.

2. Fair Market Value of the Niacor Licensing Transaction: Justifications and Rebuttal

a. Defendants' Procompetitive Justifications for the Payment

Defendants assert that the Niacor license stands on its own merit, and that the $60 million Schering paid for Niacor was a good faith, fair market value purchase of the Niacor license. (Defs.' SUF Upsher ¶¶ 18, 21-51.) Defendants first offer evidence that Schering informed Upsher several times during settlement negotiations that it would not pay money to delay Upsher's entry onto the market. (Defs.' SUF Upsher ¶¶ 15-18.) Schering's in-house counsel stated during negotiations that it would pay Upsher in a settlement only for "business deals that stand on their own two feet." (Defs.' SUF Upsher ¶ 20.) Schering also told Upsher that any

licensing deal must be valued such that Schering would have entered into it with or without the contemporaneous settlement of litigation. (Defs.' SUF Upsher ¶ 21.)

Furthermore, Defendants offer evidence to show that Schering had a genuine interest in Niacor at the time of the Schering-Upsher settlement. (Defs.' SUF Upsher ¶¶ 22-25.) Schering had previously pursued an opportunity with Kos Pharmaceuticals to co-promote Niaspan, a sustained-release niacin product, in the months before the Upsher settlement. (Defs.' SUF Upsher ¶¶ 24-25.) The talks between Schering and Kos fell through. (Defs.' SUF Upsher ¶¶ 25, 40.) At the time of the Schering-Upsher settlement, Niacor was in the late stages of development and Upsher had minimized previous issues with side effects of the drug, leading to Schering's interest in the product. (Defs.' SUF Upsher ¶¶ 26-27.)

According to Defendants, Schering also conducted an internal review of Niacor before signing the Schering-Upsher settlement, including a commercial assessment and a review of clinical trial results. (Defs.' SUF Upsher ¶¶ 29-31, 34, 35, 36-38.) Schering also created a sales forecast for Niacor outside of the United States, Canada, and Mexico. (Defs.' SUF Upsher ¶ 36.) Defendants have also produced sales projections for Niaspan which they claim support Schering's sales projections for Niacor. (Defs.' SUF Upsher ¶¶ 37-40.) Based on the sales projections, Schering head of Global Marketing Thomas Lauda testified that he believed that overseas rights to Niacor were "well worth" $60-70 million. (Defs.' SUF Upsher ¶¶ 42.)

Finally, Defendants offer evidence that Schering's Board of Directors reviewed the proposed Niacor deal prior to signing the Schering-Upsher agreement, using the same standard corporate finance model used for all license deals it reviewed. (Defs.' SUF Upsher ¶ 44.) This

model gave the present economic value[13] of the Niacor license at $225-265 million. (*Id.*) Furthermore, the Board of Directors were instructed to approve the Niacor license only if the deal could stand on its own merits, independent of the settlement of the K-Dur litigation. (Defs.' SUF Upsher ¶¶ 45-46.) The Board of Directors reviewed the sales projections and commercial assessment conducted by Schering employees on Niacor, prior to approving the Schering-Upsher settlement. (Defs.' SUF Upsher ¶ 45.)

Defendants have offered evidence that could persuade a reasonable jury that Schering paid fair market value for Niacor, and that the payment at issue in the Schering-Upsher settlement did not compensate Upsher for delaying its market entry.

b. Plaintiffs' Rebuttal of Defendants' Procompetitive Justifications for the Payment

Plaintiffs, however, have offered evidence that counters Defendants' claims and that raises a genuine dispute of material fact that the reverse payment in the Schering-Upsher settlement was not merely compensation for the Niacor license.

First, Plaintiffs offer evidence that the Schering-Upsher agreement lacked terms that would typically be present in a pharmaceutical licensing agreement, including terms the in-house Schering lawyer who drafted the Schering-Upsher agreement recommends that pharmaceutical license agreements include. (Pls.' SDF Upsher ¶ 84.) These terms include: the communication infrastructure for drug development; parties responsible for additional development work; parties responsible for regulatory filings; whether the licensee will gain access to the licensor's "know-

[13] This figure represented the net present value of the expected revenue stream for Niacor over the product's expected lifetime, after subtracting the royalties Schering would pay to Upsher. (Defs' SUF Upsher ¶ 44.)

how" as part of the license agreement; parties responsible for reporting adverse events and pharmacovigilance; whether audit rights for royalties are part of the bargain; duration of rights and obligations; publicity and publication for the licensed drug; regulatory issues in foreign countries, if related to the license; and any needed representations and warranties. (Pls.' SDF Upsher ¶¶ 84, 87.) Plaintiffs also cite the testimony of Schering head of Global Marketing Thomas Lauda on this point, who stated that, when reviewing a licensing agreement, he looks for the term (or duration) of the agreement, Schering's rights and obligations under the agreement, dispute resolution terms, termination provisions, the respective obligations of the licensing partners, identification of the party responsible for regulatory approvals, and a provision requiring the other party to exercise reasonable diligence in filing an NDA if the licensor is to provide regulatory data. (Pls.' SDF Upsher ¶ 85.) The record contains several samples of other licensing agreements to which Schering was a party. These agreements include provisions on the license's term, the obligations of the parties to commercialize the drug, respective responsibilities for research and development, and how adverse events should be reported. (Pls.' SDF Upsher ¶ 86.) Plaintiffs note that none of the provisions listed above appear in the Schering-Upsher agreement. (Pls.' SDF Upsher ¶ 87.) Plaintiffs support this observation with expert testimony stating that the Schering-Upsher agreement was missing "critical" terms, including the term of the agreement, the diligence obligations of the parties, and indemnification provisions. (Pls.' SDF Upsher ¶ 89.) The expert noted that, under this agreement, Schering was obligated to pay a large part of the bargained-for consideration upfront, whether or not the parties executed a subsequent agreement or Schering developed the Niacor product. (Pls.' SDF Upsher ¶ 88.)

Second, Plaintiffs provide evidence to show the types of due diligence a company interested in purchasing a drug license will typically conduct before the license agreement is executed. Plaintiffs also offer evidence that may indicate Schering did not conduct its typical diligence on the Niacor license. According to Schering's employees, at the time of the Schering-Upsher settlement, typically Schering reviewed the following aspects of a potential product before signing a licensing agreement: (1) the science behind the product, including necessary additional research and development; (2) the regulatory status of the product; (3) the manufacturing and supply issues; (4) the intellectual property rights and potential infringement risks; and (5) the commercial potential of the product. (Pls.' SDF Upsher ¶¶ 92-94.) Typically a large number of employees worked on these reviews. (Pls.' SDF Upsher ¶¶ 94-95.) On some drugs, Schering took over a year to conduct due diligence. (Pls.' SDF Upsher ¶ 96.) But only a single employee of Schering conducted due diligence on Niacor, over the time period of two days. (Pls.' SDF Upsher ¶ 97.) This review only examined the commercial prospects of Niacor, and did not examine potential regulatory, intellectual property, or manufacturing issues. (*Id.*) Furthermore, Schering's reviewing employee did not independently verify any of the information in the package he received on Niacor, unlike when he attempted to verify facts during his due diligence examination of Niaspan. (Pls.' SDF Upsher ¶¶ 99-100.) Plaintiffs contend that Defendants' expert, who finalized licenses for twenty products while working at Bristol Myers Squibb, never conducted such an abbreviated due diligence process as the process Schering conducted for Niacor. (Pls.' SDF Upsher ¶¶ 102-03.)

Plaintiffs offer expert testimony that, typically, parties begin to commercialize a licensed drug soon after signing a licensing agreement, but that Schering did not move to commercialize

Niacor with immediacy. (Pls.' SDF Upsher ¶¶ 104-07.) Plaintiff's expert stated that, following execution of a licensing agreement, typically a licensee will appoint responsible personnel, form joint committees to oversee product development, exchange relevant legal, scientific, development, and regulatory materials, and start communicating frequently in an effort to develop and market the product. (Pls.' SDF Upsher ¶ 104.) In contrast, in the days following the signing of the Schering-Upsher agreement, Schering's Global Marketing group was assigned to be responsible for international registration and marketing of Niacor, and the employee who conducted due diligence on Niacor was appointed to manage these efforts. (Pls.' SDF Upsher ¶ 105.) Schering made a few requests for information from Upsher, but Plaintiffs assert that no substantive information was exchanged. (Pls.' SDF Upsher ¶ 107.)

Plaintiffs also declare that multiple contemporary valuations of Niacor indicate that Schering overpaid for the Niacor license in its agreement with Upsher. (Pls.' SDF Upsher ¶¶ 109-14.) Plaintiffs offer comparative evidence of several licensing deals for sustained-release niacin products, none of which approach $60 million in value. (*Id.*)

Additionally, Plaintiffs assert that Schering failed to acknowledge substantial risks with the Niacor licensing deal in its evaluation process. First, the $60 million payment Schering made to Upsher was, at the time, Schering's largest upfront non-contingent payment ever for a license, despite the fact that the FDA had not granted Niacor marketing approval at the time of the payment. (Pls.' SDF Upsher ¶¶ 115-16.) Furthermore, Niacor was not expected to be a blockbuster drug with huge sales. (*Id.*) The Board of Directors did not discuss these issues or other potential risks for licensing Niacor in their evaluation of the settlement, despite the fact that

a Schering subsidiary employee had identified significant downsides to licensing Niaspan.[14] (Pls.' SDF Upsher ¶¶ 117-22.)

Plaintiffs also challenge Defendants' evidence on the economic value of the Niacor deal, asserting that the value of the license was significantly lower than the $60 million Schering paid Upsher. Plaintiffs offer expert quantitative analysis on this issue using three valuation methods. First, using the 25 percent rule, under which in general a licensor would expect to receive about 25 percent of the pretax profits from a licensed product, Plaintiffs' expert asserted that the $60 million payment far exceeded 25 percent of the pretax profits from expected Niacor sales. (Pls.' SDF Upsher ¶ 138.) The expert noted that the other payments outlined in the Schering-Upsher agreement for Niacor approximated 25 percent of pretax profits expected for Niacor. (*Id.*) Second, in a comparable transactions analysis, Plaintiffs' expert compared the licensing agreement for Niacor to other Schering license agreements and other sustained-release niacin licensing agreements, and found that the value of Niacor approximated the $10 million in milestones and the 10 to 15 percent royalties outlined in the Schering-Upsher agreement. (Pls.' SDF Upsher ¶ 139.) Plaintiffs' expert found that these comparable agreements could not explain the $60 million upfront payment. (*Id.*) Third, Plaintiffs' expert conducted a net present value analysis, which indicated that Niacor was not worth the $60 million Schering paid Upsher. (Pls.' SDF Upsher ¶¶ 142-43.) The expert also testified that the Schering sales forecast was predicated on faulty assumptions, including the unlikely prospect that Niacor could be approved for sale in

[14] Furthermore, the sales forecast for Niaspan in the United States may not have been analogous to the sales forecast for Niacor in Europe, given Niaspan's likely position as first mover on the market. (Pls.' SDF Upsher ¶ 123.) Europe also may not have been as receptive to niacin products as the United States was at the time, given that European doctors had access to fibrate products with the same characteristics as niacin, while American doctors did not since these drugs had not been approved for marketing in the United States. (Pls.' SDF Upsher ¶ 124.)

Europe in only one year, and that Niacor would be the only sustained-release niacin product on the market. (Pls.' SDF Upsher ¶ 140.) Plaintiffs' expert also noted that Niaspan was likely a superior product to Niacor in terms of safety, efficacy, and dosing issues, and that Niaspan could be used in conjunction with statin drugs while Niacor could not. (*Id.*)

The parties devote much of their efforts to discussing the implications of prior proceedings against Schering and Upsher before the FTC and the Eleventh Circuit. *In the Matter of Schering-Plough Corp.*, No. 9297, Initial Decision, 136 F.T.C. 956, 1092 (2002); *In the Matter of Schering-Plough Corp.*, Final Order, 136 F.T.C. 956, 1003-04 (2003); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005). Those proceedings were before another adjudicative body with different parties and a different factual record. These prior proceedings will not be considered by this Court, since it necessarily can only consider the factual record before it.

While Defendants challenge the reliability and method of Plaintiffs' experts, nevertheless Plaintiffs have put this material on the record. Although Defendants may be able to successfully impeach the expert opinions and evidence Plaintiffs have presented, Plaintiffs' evidence is sufficient to raise a genuine issue of material fact on the question of the fair market value of the Niacor license. A reasonable jury could conclude that the payment in the Schering-Upsher settlement was aimed, at least in part, to delay entry of Upsher's generic K-Dur product, not to compensate Upsher for the Niacor license. "In the event a genuinely disputed issue of fact exists regarding the reasonableness of the restraint, the determination is for the jury," given that the jury is ultimately responsible for balancing the procompetitive justifications and anticompetitive rebuttals presented by the parties under the rule of reason. *In re Ins. Brokerage Antitrust Litig.*,

618 F.3d 300, 316 n.12 (3d Cir. 2010). For these reasons, Defendants' motion for summary judgment on all claims related to the Schering-Upsher settlement is denied.

b. MOTION FOR SUMMARY JUDGMENT ON ALL CLAIMS RELATED TO THE SCHERING-ESI SETTLEMENT

Defendants have also moved for summary judgment on all claims related to the Schering-ESI settlement. On this motion, the parties primarily dispute whether Schering, Upsher, and ESI formed a single conspiracy covering all actions related to K-Dur. Plaintiffs have conceded that the Schering-ESI settlement did not cause direct competitive market harm, given that "[Plaintiffs] do not intend to prove at trial that ESI was actually delayed." (7/22/15 Hrg. Tr. at 57) [Docket Entry 859]. Rather, "[Plaintiffs] intend to prove at trial that there was a violation [of antitrust law] by means of the ESI settlement which was part of the overall conspiracy that [Plaintiffs] allege." (*Id.*) This scenario, according to Plaintiffs, would impute civil liability onto ESI for the actions of all parties to the alleged single conspiracy (Schering, Upsher, and ESI). Defendants assert that, on this record, there is no evidence of a three-party conspiracy, given that Upsher and ESI settled separately with Schering on very different terms.

i. LEGAL STANDARD

1. ANTITRUST CONSPIRACY UNDER THE SHERMAN ACT

To prevail on a Section 1 conspiracy claim under the Sherman Act, 15 U.S.C. § 1, the plaintiff must prove the existence of a single agreement that unreasonably restrains trade, whether tacit or express. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 553 (2007). "The existence of an agreement is the hallmark of a Section 1 claim. Liability is necessarily based on some form

of concerted action." [15] *In re Baby Food Antitrust Litig.*, 166 F.3d 112, 117 (3d Cir. 1999) (citation omitted); *see also Ins. Brokerage Antitrust Litig.*, 618 F.3d at 315.

The plaintiff may prove the existence of a single agreement by either direct or circumstantial evidence. Direct evidence "is explicit and requires no inferences to establish the proposition or conclusion being asserted." *InterVest, Inc. v. Bloomberg, L.P.*, 340 F.3d 144, 159 (3d Cir. 2003) (quoting *In re Baby Food Antitrust Litig.*, 166 F.3d at 118). In the absence of direct evidence of an actual agreement or conspiracy to restrain trade, finders of fact typically use proof by inferences, drawn from circumstantial evidence, to establish a violation of Section 1 of the Sherman Act. *Id.* The use of circumstantial evidence can be problematic, as finders of fact may draw incorrect inferences based on the evidence before them, and thus mistake legitimate competition for unlawful cooperation. "[M]istaken inferences in [antitrust] cases . . . are especially costly, because they chill the very conduct the antitrust laws were designed to protect"—procompetitive conduct. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986). Given this legitimate concern, the Supreme Court has found that "antitrust law limits the range of permissible inferences [that may be drawn] from ambiguous evidence in a § 1 case." *Id.* at 588. To survive summary judgment, "[t]here must be evidence that tends to exclude the possibility that the [alleged conspirators] were acting independently." *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 764 (1984). Put another way, if conduct can be

[15] The Third Circuit has noted that the term "concerted action" is generally used as shorthand to refer to any activity meeting the "contract, combination or conspiracy" element for Section 1 liability. *In re Baby Food Antitrust Litig.*, 166 F.3d at 117 n.3.

explained in an equally plausible manner by an illegal conspiracy or by permissible competition, the finder of fact is not permitted to draw an inference of conspiracy. *Id.*

2. Numbers and Types of Conspiracies

In *United States v. Kelly*, the Third Circuit adopted a three-step test to determine whether a set of events comprises a single conspiracy or separate, unrelated conspiracies. 892 F.2d 255, 259 (3d Cir. 1989) (citing *United States v. DeVarona*, 872 F.2d 114 (5th Cir. 1989)). The court first determines whether there was a common goal among the conspirators. *Id.* Second, the court examines the nature of the scheme to find whether the agreement sought to create a result that would require the "continuous cooperation of the conspirators." *Id.* (quoting *DeVarona*, 872 F.2d at 119). Finally, the court examines the level to which participants overlap in the various dealings. *Id.* "[T]he government need not prove that each defendant knew all the details, goals, or other participants in order to find a single conspiracy." *Id.* at 260 (quotation omitted). "The absence of one [*Kelly*] factor does not necessarily defeat an inference of the existence of a single conspiracy." *United States v. Padilla*, 982 F.2d 110, 115 (3d Cir. 1992). Furthermore, "courts treat civil and criminal conspiracy alike—apart of course from standard of proof and other respects in which civil and criminal procedure differ—so that the abundant precedents on the meaning of criminal conspiracy are available for use in the civil context." *Hartford Accident & Indem. Co. v. Sullivan*, 846 F.2d 377, 383 (7th Cir. 1988); *see also Interstate Circuit v. United States*, 306 U.S. 208, 227 (1939) (citing *United States v. Schenck*, 253 F. 212, 213 (E.D. Pa. 1918), *aff'd*, 249 U.S. 47 (1919) (Espionage Act) and *Levey v. United States*, 92 F.2d 688, 691 (9th Cir. 1937), *cert. denied*, 303 U.S. 639 (1938) (mail fraud) as examples of situation where a conspiracy may be formed in a civil context).

Conspiracies are often described as taking one of two forms: a "chain" conspiracy, where conspirators act separately and successively; or a "wheel" or "hub-and-spoke" conspiracy, where a central figure (the "hub") interacts separately with peripheral parties (the "spokes") in furtherance of a single, illegal enterprise. In a hub-and-spoke conspiracy, each peripheral party "spoke" is a member of the conspiracy, even though these parties may not directly interact with each other. For a single conspiracy to exist, the parties serving as spokes must have been aware of the existence of other spokes, and each spoke must have done something in furtherance of a single, illegal endeavor. *Kotteakos v. United States*, 328 U.S. 750, 755 (1946); *see also Blumenthal v. United States*, 332 U.S. 539, 556-57 (1947); *United States v. Castro*, 776 F.2d 1118, 1124 n.4 (3d Cir. 1985). The Supreme Court explained in *Kotteakos* that the existence of a single party common to several conspiracies does not necessarily establish that a single conspiracy existed between all parties in the criminal context. 328 U.S. at 755. For a single conspiracy to exist, a "rim" must connect the spokes, and typically a rim takes the form of connecting agreements between the spokes. *Total Benefits Planning Agency, Inc. v. Anthem Blue Cross & Blue Shield*, 552 F.3d 430, 435 n.3 (6th Cir. 2008); *see also Dickson v. Microsoft Corp.*, 309 F.3d 193, 203 (4th Cir. 2002) ("A rimless wheel conspiracy is one in which various defendants enter into separate agreements with a common defendant, but where the defendants have no connection with one another, other than the common defendant's involvement in each transaction.") (citing *Kotteakos*, 328 U.S. at 755). But "[i]t is elementary that an unlawful conspiracy may be and often is formed without simultaneous action or agreement on the part of the conspirators." *Interstate Circuit*, 306 U.S. at 227. Moreover, a party seeking to prove a

conspiracy "need not prove that each defendant knew all of the conspiracy's details, goals, or other participants." *United States v. Gibbs*, 190 F.3d 188, 197 (3d Cir. 1999).

The Third Circuit opinion in *United States v. Kemp* emphasized that "there must be overlap among the spokes, not just between the hub and the various spokes," to find a single hub-and-spoke conspiracy on a given set of facts. 500 F.3d 257, 291 (3d Cir. 2007). In determining whether the facts support a single or multiple conspiracies, "the inquiry must focus . . . on the character of the agreement between the spokes." *Id.* Likewise, "[i]n all hub-and-spoke conspiracies, the horizontal agreement among the spokes supports the [vertical] agreements between the hub and each spoke, and vice versa." *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d at 347.

ii. ANALYSIS

At the summary judgment stage, the movant is the party without the burden of proof at trial. Therefore, the Court must determine whether there is sufficient evidence on the question of whether Schering, Upsher, and ESI formed a single conspiracy such that the question should go to the jury.

Plaintiffs envision a single hub-and-spoke conspiracy, with Schering as the hub and with Upsher and ESI as spokes due to their respective settlements with Schering, working together to eliminate generic competition for K-Dur. In Plaintiffs' scenario, ESI would be civilly liable for all of the conspiracy's actions, including any competitive harm caused by the conspiracy's actions to delay Upsher's entry onto the market. Plaintiffs characterize Schering's payment to ESI as inducement to convince ESI to join the conspiracy with Schering and Upsher.

Conversely, Defendants assert that there is no evidence of a single three-party conspiracy on this record, given that Schering and Upsher settled their patent litigation without the involvement of ESI, and that Schering and ESI settled their patent litigation without the involvement of Upsher. According to Defendants, ESI should not be civilly liable for the Schering-Upsher settlement, because ESI knew nothing about the legality of the Schering-Upsher agreement—which hinges on whether Schering paid fair market value for the Niacor license. Under *Kotteakos* and *Kemp*, Defendants argue that because alleged spokes Upsher and ESI were not part of each other's settlement agreements, the evidence before this Court does not indicate any agreement between the spokes. Given the lack of evidence on the record that ESI would have actually won the litigation, Defendants also dispute that ESI could have entered the market with a generic version of K-Dur after winning a ruling of non-infringement in the ongoing patent case.

i. Direct Evidence of a Single Conspiracy

For this Court to treat the evidence Plaintiffs have offered as direct evidence of a single conspiracy between Schering, Upsher, and ESI, a reasonable finder of fact must be able to use the evidence to find a conspiracy with no further extrapolation. *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d at 324 n.23. If, based on the evidence presented, a finder of fact must make an additional logical step to conclude that a conspiracy occurred, the evidence is circumstantial, not direct. *Id.* Courts have found evidence such as a "document or conversation explicitly manifesting the existence of the agreement in question" to be direct evidence. *Id.*; *see also Monsanto*, 465 U.S. at 765 (finding that supplier's advice to distributors that they would be terminated if suggested price levels were not maintained was direct evidence); *InterVest*, 340

F.3d at 162-63 (listing examples of direct evidence, including "a direct threat to the plaintiff from a competitor that if he went into business his competitors would do anything they could to stop him[;]. . . a memorandum . . . detailing the discussions from a meeting of a group of alleged conspirators," and "a public resolution by a professional association recommending that its members withdraw their affiliation with an insurer" (internal quotations omitted)).

Plaintiffs have offered several types of evidence intended to directly demonstrate a conspiracy between Schering, Upsher, and ESI. Plaintiffs first offer evidence intended to show that ESI knew that Schering and Upsher had entered into an unlawful settlement. During the Schering-ESI patent litigation, ESI filed a motion to compel the production of a copy of the Schering-Upsher agreement, and in that motion stated that the Schering-Upsher agreement "may have been crafted collusively with anticompetitive purpose, and [the agreement was] therefore reasonably calculated to be admissible evidence of patent misuse or an antitrust violation." (Pls.' SDF ESI ¶ 28.) Plaintiffs also assert that Schering and ESI exchanged market forecasts predicting the potential impact of multiple versions of K-Dur on Schering, Upsher, and ESI. (Pls.' SDF ESI ¶ 24.) Finally, Plaintiffs argue that the Defendants all had similar motives to cooperate—allegedly, all parties sought to share Schering's monopoly profits through blocking the entry of generic competitors onto the K-Dur market. (Pls.' Sur-Reply Br. at 3, 9-10.)

The Court finds that none of the evidence offered by Plaintiffs is direct evidence of a single conspiracy, because it does not establish on its own any concerted action between Schering, Upsher, and ESI. Proving a violation of Section 1 of the Sherman Act requires that the parties have unlawfully agreed, not simply that the parties had the opportunity to conspire or that competitors may be aware of similar conduct by other parties. *In re Insurance Brokerage*

Antitrust Litig., 618 F.3d at 349-50. Plaintiffs do not offer a "smoking gun" to show that Defendants directly colluded, and the evidence Plaintiffs have offered is not similar to the examples of direct evidence listed above. Plaintiffs have offered no direct evidence, such as a conversation or document, that ESI and Upsher agreed amongst themselves to collude in this market, much less that all parties agreed to collude in the K-Dur market. Instead, Plaintiffs have provided evidence of agreements between Schering and Upsher (Docket Entry 843-1), and between Schering and ESI (Docket Entry 843-52). These agreements do not have similar structures or terms, as the parties agreed on different market entry dates, for different types of consideration. (*Id.*) A reasonable finder of fact would need to make inferences to conclude that these agreements indicated a single conspiracy between the parties. Thus, Plaintiffs have not provided direct evidence sufficient for a reasonable finder of fact to find a single conspiracy.

ii. Circumstantial Evidence of a Single Conspiracy

Plaintiffs urge the Court to find that the record has sufficient circumstantial evidence such that a reasonable jury could find, under the three-part test outlined in *Kelly*, that Schering, Upsher, and ESI entered into a single conspiracy to delay the entry of generic K-Dur.[16] Under Plaintiffs' theory, the conspirators shared the common goals of delaying generic competition for K-Dur, and sharing the financial benefits of such delay. Allegedly, the Schering-ESI settlement

[16] Plaintiffs offer two theories as to how ESI participated in the overall conspiracy: either ESI formed a conspiracy with Schering and Upsher, presumably at the time of the Schering-ESI agreement; or ESI joined the Schering-Upsher conspiracy already in existence at the time of the Schering-ESI agreement. It is established Third Circuit law that a party who did not participate in the formation of a conspiracy "may nevertheless join belatedly and become responsible for the actions that antedated his arrival should he knowingly 'co-operate in the common effort to obtain the unlawful results.'" *United States v. Vasquez-Uribe*, 426 F. App'x 131, 135 (3d Cir. 2011) (quoting *United States v. Lester*, 282 F.2d 750, 753 (3d Cir. 1960)). How ESI allegedly entered the single conspiracy is not outcome determinative on these facts. The Court finds that the issues of interdependence and overlap are the key issues in this analysis, and the analysis provided herein would apply in either scenario.

was one part of a larger scheme to prevent generic K-Dur from entering the market, which required Schering to eliminate all other threats to its monopoly by cooperating with all potential generic challengers. Plaintiffs base their assertions on an intricate analysis of the FDA's enforcement of the Hatch-Waxman Act's exclusivity provisions at the time of the Schering-ESI settlement, which is examined in detail below. Finally, Plaintiffs assert that there is overlap as to the parties involved in the alleged sub-conspiracies since Schering is a party to both conspiracies.

The Court finds that there is not sufficient circumstantial evidence presented here to persuade a reasonable jury that Schering, Upsher, and ESI had a common goal, sought to maintain the continuous operation of the single conspiracy, or that the parties overlap sufficiently to support an inference of a single conspiracy. In particular, Plaintiffs have failed to offer sufficient evidence of the interdependence of the Schering-Upsher and Schering-ESI settlements to support the finding of an inference of conspiracy by a reasonable finder of fact.

a. Interdependence of Alleged Conspiracies

As noted above, Plaintiffs allege that Schering, Upsher, and ESI shared the same goals: (1) delaying generic competition; and (2) sharing the financial benefits of delay, presumably through Schering's distribution of monopoly profits in settlement payments to generic companies. It is not sufficient that Plaintiffs demonstrate that Schering, Upsher, and ESI had the same goal, however. To demonstrate a single conspiracy under *Kelly*, Plaintiffs must demonstrate that the parties had a *common* goal. 892 F.2d at 259. Furthermore, Plaintiffs allege that, in order to prevent generic competition for K-Dur, Schering, Upsher, and ESI had to work together and continuously. To demonstrate both of these elements, Plaintiffs must provide evidence tending to show that the settlements were interdependent in nature. To evaluate

interdependence, the court engages in an inquiry focused on "the extent to which the success or failure of one conspiracy is independent of a corresponding success or failure by the other." *United States v. Macchia*, 35 F.3d 662, 671 (2d Cir. 1994); *see also Kemp*, 500 F.3d at 289 ("In evaluating interdependence, we consider how helpful one individual's contribution is to another's goals.").

Plaintiffs propose the following theory of motivation for Schering, Upsher, and ESI to conspire in an interdependent fashion. Plaintiffs contend that, at the time of the Schering-ESI settlement, ESI posed a competitive threat to Schering's monopoly on the K-Dur market given that under the FDA's successful defense requirement,[17] ANDA first-filer Upsher was not entitled to 180 days of marketing exclusivity. Upsher thus could not use its exclusivity period to block ESI's entry onto the market, and had it won its patent litigation with Schering, ESI could have entered the market immediately. After the FDA stopped enforcing the successful defense

[17] When Schering and ESI entered into their settlement on January 23, 1998, the FDA actively enforced a Final Rule implementing patent and marketing exclusivity provisions of the Hatch-Waxman Act known as the "successful defense requirement." 21 C.F.R. § 314.107(c)(1); Abbreviated New Drug Applications, 59 Fed. Reg. 50338, 50367 (Oct. 3, 1994). Under this requirement, a first-filer ANDA applicant using a Paragraph IV certification was not entitled to receive the statutory 180-day exclusivity period unless it had successfully defended a patent infringement suit. *Id.* Litigants challenged these requirements, and the District of the District of Columbia ruled in *Inwood Laboratories, Inc. v. Young*, 723 F. Supp. 1523 (D.D.C. 1989), *vacated as moot*, 43 F.3d 712 (D.C. Cir. 1989), and *Mova Pharmaceutical Corp. v. Shalala*, 955 F. Supp. 128 (D.D.C. 1997), that the 180-day marketing exclusivity period should be granted to the first ANDA applicant who files a Paragraph IV certification for a specific generic drug, whether or not the applicant is sued subsequently for patent infringement. Conversely, the Eastern District of North Carolina ordered the FDA to enforce the successful defense requirement in its decision in *Granutec, Inc. v. Shalala*, No. 5:97-cv-485, 1997 WL 1403894 (E.D.N.C. July 3, 1997). In response to these decisions, the FDA published a policy clarification on November 28, 1997 that reiterated its intent to continue its enforcement of the successful defense requirement, at least until appeals in the 1997 cases had been completed. FDA, Policy on 180-Day Marketing Exclusivity for Drugs Marketed Under Abbreviated New Drug Applications; Clarification (Nov. 28, 1997). Following the decisions from Courts of Appeal in *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998) and *Granutec, Inc. v. Shalala*, 139 F.3d 889 (4th Cir. 1998) (unpublished opinion) that both overturned the successful defense requirement, the FDA expressed its intent to no longer enforce the requirement as of June 1998. HHS Center for Drug Evaluation and Research (CDER), Guidance for Industry: 180-Day Generic Drug Exclusivity under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (June 1998).

requirement in June 1998, Plaintiffs assert that ESI could have triggered[18] Upsher's newly-instated exclusivity period by winning its patent litigation against Schering, even before Upsher had the right to enter the market per its agreement with Schering. Under this scenario, ESI could have entered the market as a competitor to Schering after Upsher's exclusivity expired. According to Plaintiffs, Schering's payment to ESI eliminated the threat that ESI would enter the market before January 2004, which benefitted both Schering and Upsher. Schering's payment also prevented ESI from triggering Upsher's exclusivity period before Upsher could enter the market in September 2001, and so gave Upsher a reason to collude with ESI. Plaintiffs further assert that Schering provided ESI incentive to collude with the overall conspiracy through the cash payment included in the Schering-ESI settlement.

To find a single conspiracy, a rim must have connected the spokes Upsher and ESI, as a single conspiracy can only be found where "the evidence clearly indicated that the defendants would not have undertaken their common action without reasonable assurances that all would act in concert." *In re Insurance Brokerage Antitrust Litig.*, 618 F.3d at 332. In essence, the transactions must have been contingent on each other to establish interdependence. *Kemp*, 500 F.3d at 291. Plaintiffs bear the burden to offer evidence tending to indicate that the spokes of the alleged single conspiracy made some kind of agreement, whether explicit or tacit.

[18] As noted above, a first-filer ANDA applicant may receive 180 days of exclusivity upon the earlier of the first commercial marketing of the first-filer's generic drug under its ANDA, or a court decision of patent invalidity or non-infringement, which "triggers" the start of the exclusivity period. A court decision triggering the exclusivity period need not involve the first-filing ANDA applicant, however. A subsequent ANDA filer may obtain a ruling of invalidity or non-infringement, and that ruling triggers the first-filer ANDA applicant's exclusivity period. *Minn. Mining & Mfg. Co. (3M) v. Barr Labs., Inc.*, 139 F. Supp. 2d 1109 (D. Minn. 2001), *aff'd*, 289 F.3d 775 (Fed. Cir. 2002).

The Court finds that Plaintiffs have not put sufficient evidence onto the record to support their theory, such that a reasonable finder of fact could conclude that the Schering-Upsher and Schering-ESI deals were interdependent. Plaintiffs assert that the settlements were interdependent because Schering had to settle with both Upsher and ESI to guarantee that it would be free of generic competition until Upsher entered the market in September 2001. This theory indicates a possible motivation for Schering to collude with Upsher and with ESI, as Schering's success in the K-Dur market may have depended on the agreements it made with Upsher and ESI. Theories about one party's motivations in entering into a settlement are not evidence of a conspiracy, however, particularly on these facts where the Court's inquiry must necessarily focus on the evidence related to the interdependence or horizontal agreement between alleged spokes Upsher and ESI. Likewise, awareness of a competitor's actions is not enough to create an inference of a conspiracy. *See In re Insurance Brokerage Antitrust Litig.*, 618 F.3d at 349-50. For ESI in particular, its awareness that Schering and Upsher had settled their patent litigation, even on potentially anticompetitive terms, does not establish a single conspiracy. Plaintiffs point to no other evidence that would indicate ESI's motive in settling with Schering somehow involved an interest in entering into a single, overall conspiracy.

Moreover, the evidence before this Court does not suggest that Upsher and ESI in any way interfered with the other party's settlement with Schering. Upsher and ESI structured different deals with Schering, supporting an inference that their goals in settling their respective patent litigations were not interdependent.[19] The plain language of the settlements at issue in this

[19] The Court notes that two recent district court decisions have examined whether a single conspiracy existed with a brand-name pharmaceutical company who entered into basically the same settlement agreement, including a reverse payment, with several generic companies. *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, No. 06-1797, 2014

case does indicate that both Upsher and ESI sought market entry prior to patent expiration, and that a term of ending patent litigation against Schering was a cash payment. But Upsher and ESI negotiated with Schering for different settlement dates, and arranged different payment amounts and schedules. Furthermore, Plaintiffs have offered no evidence that Upsher acted with the involvement of ESI in settling with Schering. Upsher also had no knowledge at the time of the Upsher-Schering settlement that ESI eventually would settle with Schering. Upsher knew ESI and Schering were engaged in patent litigation at the time of its settlement with Schering, and that, if ESI won that litigation before Upsher's settlement entry date of September 1, 2001, that ESI would be able to enter the market before Upsher. (Docket Entry 843-1.)

Plaintiffs likewise have not offered sufficient evidence to show that ESI's settlement with Schering was dependent on Upsher or the Schering-Upsher settlement. In fact, Upsher's settlement likely did not affect ESI's ability to enter the market in January 1998. At the time of the Schering-ESI settlement, Upsher had not satisfied the successful defense requirement,

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WL 2813312 (E.D. Pa. June 23, 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231 (D. Mass. 2014). In the settlement agreements, each generic company agreed to enter the market on the same date, with a contingent launch provision. The court in *King Drug Co.* granted summary judgment on the issue of a single conspiracy between the brand-name and generic manufacturers. No. 06-1797, 2014 WL 2813312, at *14 (E.D. Pa. June 23, 2014). Conversely, the court in *In re Nexium* denied summary judgment on the issue of a single conspiracy. 42 F. Supp. 3d at 258. Both courts compared their fact pattern to two hub-and-spoke conspiracy cases in which the hub made the same agreement with a series of spokes: *Interstate Circuit*, 306 U.S. at 215-16, and *Toys "R" Us, Inc. v. FTC*, 221 F.3d 928, 930, 935-36 (7th Cir. 2000). These cases relied on findings of interdependence and the presence of "plus factors," predominantly an assessment of each spoke's economic interest, to establish that the parties tacitly cooperated. *See Interstate Circuit*, 306 U.S. at 222; *Toys "R" Us*, 221 F.3d at 936. *In re Nexium*, *King Drug Co.*, *Interstate Circuit*, and *Toys "R" Us* are all distinguishable from the instant case, because all of the alleged spokes in those cases made the same vertical agreement with their respective hub, at or around the same time. But the Schering-Upsher and Schering-ESI settlements differ in their material terms. Schering's settlement with Upsher set a different generic entry date from the Schering-ESI settlement, and the generic companies did not receive the same consideration for their agreements. (Docket Entry 843, Ex. 1; Docket Entry 843-52.) Unlike in the cases referenced above, the parties in this case did not settle in a near-contemporaneous fashion: Schering settled with Upsher in June 1997, while Schering settled with ESI in January 1998. (*Id.*)

because it settled with Schering in June 1997 rather than successfully defending Schering's patent suit.[20] Under the successful defense requirement, the first generic to file an ANDA with a Paragraph IV certification could not receive the 180-day exclusivity period unless it successfully defended a patent infringement suit. 21 C.F.R. § 314.107(c)(1); Abbreviated New Drug Applications, 59 Fed. Reg. 50338, 50367 (Oct. 3, 1994). Accordingly, Upsher arguably could not have used its exclusivity right to block ESI's entry into the market in January 1998, and therefore ESI could not have triggered Upsher's 180 days of exclusivity by winning its patent litigation at this time. ESI could have reached the market earlier if it had won its patent litigation with Schering, given these facts. But none of this evidence suggests that Upsher and ESI had motives to collude with each other. In fact, if ESI had been able to trigger Upsher's exclusivity period, Upsher may have had an incentive to collude with ESI to protect its exclusivity right. But Upsher faced no such threat from ESI. Plaintiffs' arguments about ESI's potential behavior if it had chosen to continue litigation against Schering after the demise of the successful defense requirement in June 1998 are pure speculation, not supported by the evidence before this Court, and will not be entertained.

[20] *See, e.g., In re K-Dur Antitrust Litig.*, No. 1-1652, 2009 WL 508869, at *24 (D.N.J. Feb. 6, 2009) (noting that the agreements in this case did not manipulate the 180-day exclusivity period to create a "bottleneck" blocking the entry of other generic companies onto the market, as Upsher could have transferred or relinquished its exclusivity right, and furthermore that because the successful defense requirement existed when Schering and Upsher settled, "Upsher arguably was not entitled to the exclusivity period."); *see also In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003), *aff'd*, 466 F.3d 187 (2d Cir. 2006) (as amended), *abrogated by FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). In 1985, generic manufacturer Barr filed the first ANDA with a Paragraph IV notice for tamoxifen, a treatment for breast cancer. 277 F. Supp. 2d at 124-25. Brand-name manufacturer Zeneca and Barr settled the ensuing patent litigation in 1993. *Id.* Subsequently, several other generic manufacturers filed ANDAs for tamoxifen in 1994 and 1996. *Id.* at 126-27. While the suits related to these subsequent ANDAs were pending in district court, the FDA stopped enforcing the successful defense requirement. 466 F.3d at 195. The Second Circuit noted that the successful defense requirement "would have excluded Barr from benefitting from the exclusivity period," given that it settled with Zeneca. *Id.* In June 1998, after the FDA removed the successful defense requirement, Barr attempted to block final FDA approval of other generic versions of tamoxifen by asserting its rights to the 180-day exclusivity period. *Id.*

In light of the reasoning above, the Court finds that Plaintiffs have not established that a rim existed between spokes Upsher and ESI. There is a dearth of evidence on which a reasonable jury could conclude that the Schering-Upsher and Schering-ESI agreements were interdependent, as would be required to support an inference of a single conspiracy between Schering, Upsher, and ESI. Given that Plaintiffs must show that it is more likely than not that a single conspiracy was formed, Plaintiffs have not made the requisite evidentiary showing on the issue of interdependence to support such a claim.

b. Overlap of Alleged Conspirators

Furthermore, Plaintiffs' view of what constitutes sufficient overlap between the parties under *Kelly* does not comport with established Third Circuit case law regarding hub-and-spoke conspiracies. Plaintiffs assert that they have satisfied the third element of the *Kelly* test by noting that Schering, the alleged hub in the overall hub-and-spoke conspiracy, is a member of both alleged sub-conspiracies. But the Supreme Court has ruled that the presence of a single party common to several illegal agreements with other parties does not necessarily establish a single conspiracy. *Kotteakos*, 328 U.S. at 755. Plaintiffs also ignore the Third Circuit opinions that require the showing of at least a reasonable inference of a horizontal agreement between the spokes of a hub-and-spoke conspiracy to find a single conspiracy, not just vertical agreement between the hub and each individual spoke. *See, e.g.*, *Kemp*, 500 F.3d at 291 (finding that when determining whether the facts support a single or multiple conspiracies, "the inquiry must focus . . . on the character of the agreement between the spokes"); *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d at 347 ("In all hub-and-spoke conspiracies, the horizontal agreement among the spokes supports the agreements between the hub and each spoke, and vice versa").

Under *Kotteakos*, Plaintiffs have not offered evidence such that a finder of fact could reasonably determine that the spokes of the alleged hub-and-spoke conspiracy—Upsher and ESI—made any type of horizontal agreement or overlapped in any other way. On this point, Plaintiffs discuss the motives of Schering in wishing to end the threat of generic competition for K-Dur, and assert that Upsher and ESI were incentivized to enter into the conspiracy through Schering's payments. But Plaintiffs do not offer facts that this Court can construe as showing any type of agreement between Upsher and ESI. In fact, as part of the settlement with Schering, Upsher agreed to not assist ESI with its ongoing patent litigation against Schering, and to not assist any other party challenging the '743 patent. (Docket Entry 843, Ex. 1 ¶ 6.) And there is no evidence on this record that ESI even knew about the Schering-Upsher settlement until after it occurred.

Plaintiffs cannot succeed on the third *Kelly* factor simply by showing that both Upsher and ESI settled with Schering, and then asking the Court to infer that the parties had illegal motives for settling. As discussed above, Plaintiffs' evidence does not establish that ESI had a motive to enter into a single conspiracy, that Upsher and ESI acted in a collusive manner by interacting or agreeing in any sort of horizontal manner, or that ESI would have benefitted from some sort of tacit agreement to collude with Schering and Upsher.

Plaintiffs have not satisfied their burden on the issue of overlap by stating that ESI knew about the alleged conspiracy between Schering and Upsher, or even by stating that in court documents, ESI acknowledged that the Schering-Upsher settlement may have been anticompetitive. (Pls.' SDF ESI ¶ 28; Defs.' SDF Reply ESI ¶ 28.) Plaintiffs must present evidence tending to show either that ESI agreed to join the Schering-Upsher conspiracy, or that it

formed a conspiracy with Schering and Upsher at the time it signed a settlement agreement with Schering, and furthermore that ESI knowingly cooperated in the common effort to obtain unlawful results. On this evidence, no reasonable jury could conclude that it is more likely that ESI joined a single conspiracy with Schering and Upsher rather than that ESI bargained with Schering for its own benefit.

Plaintiffs have not provided sufficient direct or circumstantial evidence such that a reasonable finder of fact could find in favor of Plaintiffs on the issue of a single conspiracy between Schering, Upsher, and ESI. Plaintiffs have thus failed to cite evidence sufficient to defeat Defendants' summary judgment motion, and accordingly the Court will grant Defendants' motion for summary judgment on all claims related to the Schering-ESI settlement.

V. CONCLUSION

For the foregoing reasons, the Court will deny as moot Plaintiffs' motion to strike Sections I and II of Defendants' reply memorandum related to the ESI settlement. The Court will also deny Defendants' motion for summary judgment as to all claims brought by Plaintiffs related to the Schering-Upsher settlement. The Court will grant Defendants' motion for summary judgment as to all claims brought by Plaintiffs related to the Schering-ESI settlement. An appropriate Order will be filed herewith.

s/ Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge

Dated: February 25, 2016